PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P 02 109 WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/DK 02/00627	24.09.2002	24.09.2002
International Patent Classification (IPC) or both national classification and IPC		
A23G3/30		
Applicant		
GUMLINK A/S et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 10 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
08.03.2004	20.12.2004
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK 02/00627

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-30 as originally filed

Claims, Numbers

1-64 filed with telefax on 26.11.2004

Drawings, Sheets

1-14 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-64
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-64
Industrial applicability (IA)	Yes:	Claims	1-64
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: EP-A-0 711 506 (UNIV GRONINGEN) 15 May 1996 (1996-05-15)

D2: WO 01/47368 A (PATEL BHARAT KANAIYALAL ;GOLDBERG DANIEL (US); EATON ROBERT FRANCI) 5 July 2001 (2001-07-05)

D3: WO 00/19837 A (LI WEISHENG ;WRIGLEY W M JUN CO (US)) 13 April 2000 (2000-04-13)

Novelty:

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

A chewing gum comprising at least two different biodegradable polymers, wherein said at least two different biodegradable polymers have a different glass transition temperature is D3. See in particular, claims 1, 5 and 9 in D1. The different molecular weights defined in claims 5 and 9 lead obviously to different glass temperature of the two different biodegradable polymers in D3.

Inventive step:

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-64 does not involve an inventive step in the sense of Article 33(3) PCT.

The use of at least two different biodegradable polymers having a different glass transition temperature, in chewing gums with the desired characteristics has been already made obvious in the above cited prior art document D3. See e.g. page 17, l. 18-19 where it is stated that the chewing texture of the gum of D3 is like a conventional chewing gum.

Thus, the presently posed problem has been solved in a similar manner by document D3.

Dependent claims 2-64 do not seem to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step.

Claims

1. Chewing gum comprising at least two different biodegradable polymers.

2. Chewing gum according to claim 1,
wherein the at least two different polymers are hydrophilic.

3. Chewing gum according to claim 1 or 2,
wherein the difference in molecular weight between the at least two different polymers is at least 1000 g/mol Mn

4. Chewing gum according to any of the claims 1 - 3,
wherein the difference in molecular weight between the at least two different polymers is at least 50000 g/mol Mn

5. Chewing gum according to any of the claims 1 - 4,
wherein at least one of said at least two different biodegradable polymers comprises a biodegradable elastomer and

at least one of said at least two different biodegradable polymers comprises a biodegradable plasticizer, said biodegradable plasticizer comprising at least one biodegradable polymer.

6. Chewing gum according to any of the claims 1 - 5,
wherein the molecular weight of said biodegradable plasticizer is in the range of 500 - 19.000 g/mol, preferably within the range of 1.500 - 9.000 g/mol Mn.

7. Chewing gum according to any of the claims 1 - 3,
wherein said at least two different biodegradable polymers have a different glass transition temperature Tg.

8. Chewing gum according to any of the claims 1 - 7, wherein

said at least two different biodegradable polymers have a different glass transition temperature Tg.

9. Chewing gum according to any of the claims 1 -8,
wherein at least one of the applied biodegradable polymers, preferably a plasticizer, has a glass transition of at least +1°C.

10. Chewing gum according to any of the claims 1 –9,
wherein at least one of the applied biodegradable polymers, preferably a plasticizer, has a glass transition of at least +10°C.

11. Chewing gum according to any of the claims 1 –10,
wherein at least one of the applied biodegradable polymers, preferably a plasticizer, has a glass transition of at least +20°C.

12. Chewing gum according to any of the claims 1 –11,
wherein at least one of the applied biodegradable polymers comprises a biodegradable elastomer.

13. Chewing gum according to any of the claims 1 – 12,
wherein the molecular weight of said biodegradable elastomer is in the range of 10000 - 1000000 g/mol Mn, preferably within the range of 30000 - 250000 g/mol Mn.

14. Chewing gum according to any of the claims 1 – 13,
wherein at least one of the at least two different biodegradable polymers has a glass transition temperature of less than 0 °C.

15. Chewing gum according to any of the claims 1 – 14,
wherein at least one of the at least two different biodegradable polymers has a glass transition temperature of less than -30°C, preferably less than –50°C

16. Chewing gum according to any of the claims 1 –15, wherein the resulting chewing gum has at least two different glass transitions temperatures Tg.

17. Chewing gum according to any of the claims 1 –16,
wherein the chewing gum comprises
at least one biodegradable elastomer having a glass transition temperature Tg below 0°C and
at least one biodegradable plasticizer having a glass transition temperature Tg exceeding 0°C.

18. Chewing gum according to any of the claims 1 –17,
wherein the at least one plasticizer comprises at biodegradable polymer obtained by polymerization of one or more cyclic esters.

19. Chewing gum according to any of the claims 1 –18,
wherein the at least one elastomer comprises a biodegradable polymer obtained by polymerization of one or more cyclic esters.

20. Chewing gum according to any of the claims 1 – 19,
wherein the at least one elastomer comprises edible polyesters.

21. Chewing gum according to any of the claims 1 – 20,
wherein the at least one elastomer comprises edible polyesters or polyhydroxyalkanoates.

22. Chewing gum according to any of the claims 1-21,
wherein said chewing gum comprises
at least one biodegradable elastomer in the amount of about 0.5 to about 70% wt of the chewing gum,
at least one biodegradable plasticizer in the amount of about 0.5 to about 70% wt of the chewing gum and

at least one chewing gum ingredient chosen from the groups of softeners, sweeteners, flavoring agents, active ingredients and fillers in the amount of about 2 to about 80% wt of the chewing gum.

23. Chewing gum according to any of the claims 1 to 22, wherein the at least one biodegradable polymer comprises at least 25% of the chewing gum polymers, preferably at least 50%.

24. Chewing gum according to any of the claims 1 to 23, wherein all the biodegradable polymers comprised in the chewing gum comprise at least 25%, preferably at least 50% of the chewing gum polymers.

25. Chewing gum according to any of the claims 1 to 24, wherein all the biodegradable polymers comprised in the chewing gum comprise at least 80%, preferably at least 90% of the chewing gum polymers.

26. Chewing gum according to any of the claims 1 to 25, wherein the chewing gum is substantially free of non-biodegradable polymers.

27. Chewing gum according to any of the claims 1 to 26, wherein the chewing gum is free of non-biodegradable polymers.

28. Chewing gum according to any of the claims 1- 27, wherein said chewing gum ingredients comprise flavoring agents.

29. Chewing gum according to any of the claims 1- 28, wherein said flavoring agents comprise natural and synthetic flavorings in the form of natural vegetable components, essential oils, essences, extracts, powders, including acids and other substances capable of affecting the taste profile.

30. Chewing gum according to any of the claims 1-29,

wherein said chewing gum comprises flavor in the amount of 0.01 to about 30 wt %, said percentage being based on the total weight of the chewing gum.

31. Chewing gum according to any of the claims 1-30,
wherein said chewing gum comprises flavor in the amount of 0.2 to about 4 wt %, said percentage being based on the total weight of the chewing gum.

32. Chewing gum according to any of the claims 1- 31,
wherein said flavor comprises water soluble ingredients.

33. Chewing gum according to any of the claims 1-32,
wherein said water soluble flavor comprises acids.

34. Chewing gum according to any of the claims 1-33,
wherein said flavor comprises water insoluble ingredients.

35. Chewing gum according to any of the claims 1- 34,
wherein said chewing gum ingredients comprise sweeteners.

36. Chewing gum according to any of the claims 1-35,
wherein said sweetener comprises bulk sweeteners.

37. Chewing gum according to any of the claims 1-36,
wherein the chewing gum comprises bulk sweeteners in the amount of about 5 to about 95% by weight of the chewing gum, more typically about 20 to about 80% by weight of the chewing gum.

38. Chewing gum according to any of the claims 1-37,
wherein said sweetener comprises high intensity sweeteners.

39. Chewing gum according to any of the claims 1-38,

wherein the high intensity sweeteners comprise sucralose, aspartame, salts of acesulfame, alitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizin, dihydrochalcones, thaumatin, monellin, sterioside, alone or in combination

40. Chewing gum according to any of the claims 1-39,
wherein the chewing gum comprises high intensity sweeteners in the amount of about 0 to about 1% by weight of the chewing gum, more typically about 0.05 to about 0.5 % by weight of the chewing gum.

41. Chewing gum according to any of the claims 1- 40,
wherein the chewing gum comprises at least one softener.

42. Chewing gum according to any of the claims 1- 41,
wherein the at least one softener comprises tallow, hydrogenated tallow, hydrogenated and partially hydrogenated vegetable oils, cocoa butter, glycerol monostearate, glycerol triacetate, lecithin, mono-, di- and triglycerides, acetylated monoglycerides, fatty acids - such as stearic, palmitic, oleic and linoleic acids, waxes, PGE and mixtures thereof.

43. Chewing gum according to any of the claims 1- 42,
wherein the chewing gum comprises softeners in the amount of about 0 to about 18% by weight of the chewing gum, more typically about 0 to about 12 % by weight of the chewing gum.

44. Chewing gum according to any of the claims 1- 43,
wherein said chewing gum ingredients comprise active ingredients.

45. Chewing gum according to any of the claims 1- 44, said active ingredients being selected from the group of: Acetaminophen, Acetylsalicylsyre Buprenorphine Bromhexin Celcoxib Codeine, Diphenhydramin, Diclofenac, Etoricoxib, Ibuprofen, Indometacin, Ketoprofen, Lumiracoxib, Morphine, Naproxen, Oxycodon, Parecoxib, Piroxicam, Pseudoefedrin, Rofecoxib, Tenoxicam, Tramadol, Valdecoxib,

Calciumcarbonat, Magaldrate, Disulfiram, Bupropion, Nicotine, Azithromycin, Clarithromycin, Clotrimazole, Erythromycin, Tetracycline, Granisetron, Ondansetron, Prometazin, Tropisetron, Brompheniramine, Ceterizin, leco-Ceterizin, Chlorcyclizine, Chlorpheniramin, Chlorpheniramin, Difenhydramine, Doxylamine, Fenofenadin, Guaifenesin, Loratidin, des-Loratidin, Phenyltoloxamine, Promethazin, Pyridamine, Terfenadin, Troxerutin, Methyldopa, Methylphenidate, Benzalcon. Chloride, Benzeth. Chloride, Cetylpyrid. Chloride, Chlorhexidine, Ecabet-sodium, Haloperidol, Allopurinol, Colchinine, Theophylline, Propanolol, Prednisolone, Prednisone, Fluoride, Urea, Miconazole, Actot, Glibenclamide, Glipizide, Metformin, Miglitol, Repaglinide, Rosiglitazone, Apomorfin, Cialis, Sildenafil, Vardenafil, Diphenoxylate, Simethicone, Cimetidine, Famotidine, Ranitidine, Ratinidine, cetrizin, Loratadine, Aspirin, Benzocaine, Dextrometorphan, Ephedrine, Phenylpropanolamine, Pseudoephedrine, Cisapride, Domperidone, Metoclopramide, Acyclovir, Dioctylsulfosucc., Phenolphtalein, Almotriptan, Eletriptan, Ergotamine, Migea, Naratriptan, Rizatriptan, Sumatriptan, Zolmitriptan, Aluminium salts, Calcium salts, Ferro salts, Silver salts, Zinc-salte, Amphotericin B, Chlorhexidine, Miconazole, Triamcinolonacetonid, Melatonine, Phenobarbitol, Caffeine, Benzodiazepiner, Hydroxyzine, Meprobamate, Phenothiazine, Buclizine, Brometazine, Cinnarizine, Cyclizine, Difenhydramine, Dimenhydrinate, Buflomedil, Amphetamine, Caffeine, Ephedrine, Orlistat, Phenylephedrine, Phenylpropanolamin, Pseudoephedrine, Sibutramin, Ketoconazole, Nitroglycerin, Nystatin, Progesterone, Testosterone, Vitamin B12, Vitamin C, Vitamin A, Vitamin D, Vitamin E, Pilocarpin, Aluminiumaminoacetat, Cimetidine, Esomeprazole, Famotidine, Lansoprazole, Magnesiumoxide, Nizatide and/or Ratinidine or derivates and mixtures thereof.

46. Chewing gum according to any of the claims 1-45,
wherein the chewing gum is substantially free of non-biodegradable polymers.

47. Chewing gum according to any of the claims 1-46,
wherein the at least two ore more cyclic esters are selected from the groups of glycolides, lactides, lactones, cyclic carbonates or mixtures thereof.

48. Chewing gum according to any of the claims 1-47, wherein lactone monomers are chosen from the group of ε-caprolactone, δ-valerolactone, γ-butyrolactone, and β-propiolactone. It also includes ε-caprolactones, δ-valerolactones, γ-butyrolactones, or β-propiolactones that have been substituted with one or more alkyl or aryl substituents at any non-carbonyl carbon atoms along the ring, including compounds in which two substituents are contained on the same carbon atom.

49. Chewing gum according to any of the claims 1-48, wherein the carbonate monomer is selected from the group of trimethylene carbonate, 5-alkyl-1,3-dioxan-2-one, 5,5-dialkyl-1,3-dioxan-2-one, or 5-alkyl-5-alkyloxycarbonyl-1,3-dioxan-2-one, ethylene carbonate, 3-ethyl-3-hydroxymethyl, propylene carbonate, trimethylolpropane monocarbonate, 4, 6dimethyl-1, 3-propylene carbonate, 2, 2-dimethyl trimethylene carbonate, and 1, 3-dioxepan-2-one and mixtures thereof.

50. Chewing gum according to any of the claims 1- 49, wherein cyclic ester polymers and their copolymers resulting from the polymerization of cyclic ester monomers include, but are not limited to : poly (L-lactide) ; poly (D-lactide) ; poly (D, L-lactide) ; poly (mesolactide) ; poly (glycolide) ; poly (trimethylenecarbonate) ; poly (epsilon-caprolactone) ; poly (L lactide-co-D, L-lactide) ; poly (L-lactide-co-meso-lactide) ; poly (L-lactide co-glycolide) ; poly (L-lactide-co-trimethylenecarbonate) ; poly (L-lactide co-epsilon-caprolactone) ; poly (D, L-lactide-co-meso-lactide) ; poly (D, L lactide-co-glycolide) ; poly (D, L-lactide-co-trimethylenecarbonate) ; poly (D, L-lactide-co-epsilon-caprolactone) ; poly (meso-lactide-co glycolide) ; poly (meso-lactide-co-trimethylenecarbonate) ; poly (meso lactide-co-epsilon-caprolactone) ; poly (glycolide-cotrimethylenecarbonate) ; poly (glycolide-co-epsilon-caprolactone).

51. Chewing gum according to any of the claims 1-50,

wherein the chewing gum comprises filler.

52. Chewing gum according to any of the claims 1- 51,
wherein the chewing gum comprises filler in an amount of about 0 to about 50% by weight of the chewing gum, more typically about 10 to about 40 % by weight of the chewing gum.

53. Chewing gum according to any of the claims 1-52,
wherein the chewing gum comprises at least one coloring agent.

54. Chewing gum according to any of the claims 1-53,
wherein the chewing gum is coated with an outer coating.

55. Chewing gum according to any of the claims 1-54,
wherein the outer coating is a hard coating.

56. Chewing gum according to any of the claims 1-55,
wherein the hard coating is a coating selected from the group consisting of a sugar coating and a sugarless coating and a combination thereof.

57. Chewing gum according to any of the claims 1-56,
wherein the hard coating comprises 50 to 100% by weight of a polyol selected from the group consisting of sorbitol, maltitol, mannitol, xylitol, erythritol, lactitol and isomalt.

58. Chewing gum according to any of the claims 1-57,
wherein the outer coating is an edible film comprising at least one component selected from the group consisting of an edible film-forming agent and a wax.

59. Chewing gum according to any of the claims 1-58,

wherein the film-forming agent is selected from the group consisting of a cellulose derivative, a modified starch, a dextrin, gelatine, shellac, gum arabic, zein, a vegetable gum, a synthetic polymer and any combination thereof.

60. Chewing gum according to any of the claims 1-59,
wherein the outer coating comprises at least one additive component selected from the group consisting of a binding agent, a moisture absorbing component, a film forming agent, a dispersing agent, an antisticking component, a bulking agent, a flavouring agent, a coloring agent, a pharmaceutically or cosmetically active component, a lipid component, a wax component, a sugar, an acid and an agent capable of accelerating the after-chewing degradation of the degradable polymer.

61. Chewing gum according to any of the claims 1-60,
wherein the outer coating is a soft coating.

62. Chewing gum according to any of the claims 1-61,
wherein the soft coating comprises a sugar free coating agent.

63. Chewing gum according to any of the claims 1-62,
wherein said chewing gum comprises conventional chewing gum polymers or resins.

64. Chewing gum according to any of the claims 1-63,
wherein the at least one biodegradable polymer comprises at least 5% of the chewing gum polymers.

65. Chewing gum according to any of the claims 1-64,
wherein all the biodegradable polymers comprised in the chewing gum comprise at least 25%, preferably at least 50% of the chewing gum polymers.

66. Chewing gum according to any of the claims 1-65,
wherein all the biodegradable polymers comprised in the chewing gum comprise at least 80%, preferably at least 90% of the chewing gum polymers.

67. Gum base according to any of the claims 1-65.